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*The user should read all instructions before using the device.

PRODUCT DESCRIPTIONS - VED®



1. Cylinder. The cylinder serves as a vacuum chamber to allow for increased blood flow to the penis.



2. VED® ULTRA Battery-Powered Pump (with 2 AA Batteries)

This is the vacuum source with a built-in safety limiter and vacuum release button. The VED ULTRA consists of a vacuum cylinder that fits over the penis, and a battery operated vacuum pump that is attached to the cylinder. The cylinder and vacuum pump create a vacuum to draw enough blood into the penis to make it rigid.



3. VED® CLASSIC Manual Vacuum Pump. Vacuum source with built-in safety limiter and vacuum release mechanism. The VED CLASSIC consists of a vacuum cylinder that fits over the penis, a vacuum pump that is attached to the cylinder with a connecting tube and end cap. The cylinder and vacuum pump create a vacuum to draw enough blood into the penis to make it rigid.



4. Cylinder with removable End Cap to be used with the CLASSIC.

The cylinder serves as a vacuum chamber to allow for increased blood flow to the penis.



5. Connecting Tube. The connecting tube is used to connect the cylinder with end cap to the manual vacuum pump. End fittings are universal and may be attached to either component.



6. Sizing Insert. The sizing insert is used to adjust the size of the cylinder opening to fit a man's personal needs. Its use is optional.



7. Sensation Seal. The Sensation Seal is to be used on the end of the cylinder to create a seal around the penis while using the vacuum device. The Seal comes in four sizes, 3, 5, 7, and 9 to adjust to your needs. See page 14 for ordering details.

PRODUCT DESCRIPTIONS - VED®



8. Personal Lubricant. This water-based lubricant is required for proper function of the device. See page 14 for ordering information for additional lubricant.



sleeve cone adaptor

9. Loading Cone System. The sleeve and cone are needed for the applying the SoftTouch™ Constriction Seal to the base of the penis. The adaptor and cone are used for ease of loading the constriction rings onto the cylinder. (If your kit does not come with a loading cone you may purchase one as an accessory.)



10. Soft Touch™ Constriction Seal. The Soft Touch™ Constriction Seal is used to maintain an erection. Soft Touch™ provides maximum comfort and efficiency. This product must be used with the Loading Cone System.



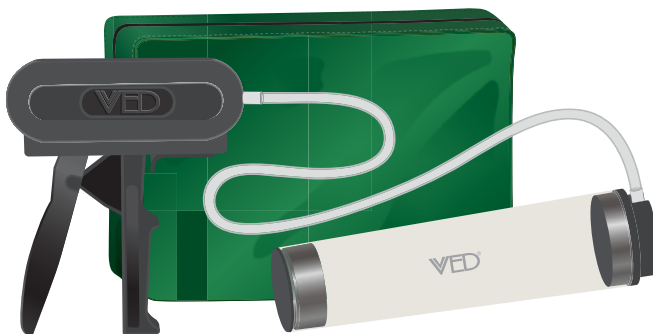
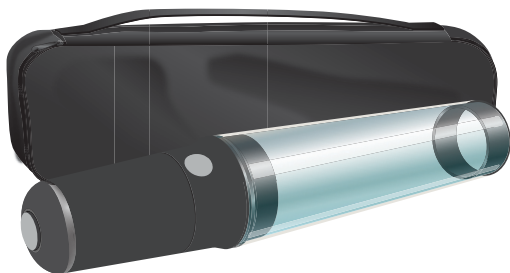
11. Constriction Rings. Constriction Rings are used to maintain an erection. Sizes are available in 3, 4, 5, 6, 7, and 8. Experiment until the constriction needed to maintain an erection is found. See page 14 for information about ordering additional constriction rings as replacement parts.



12. Instruction Manual. Reading the manual will increase satisfaction and make the VED® easier to use.



13. Instructional DVD. This DVD demonstrates proper use of the VED® for the purpose of intercourse and therapy.



INTENDED USE AND INDICATIONS

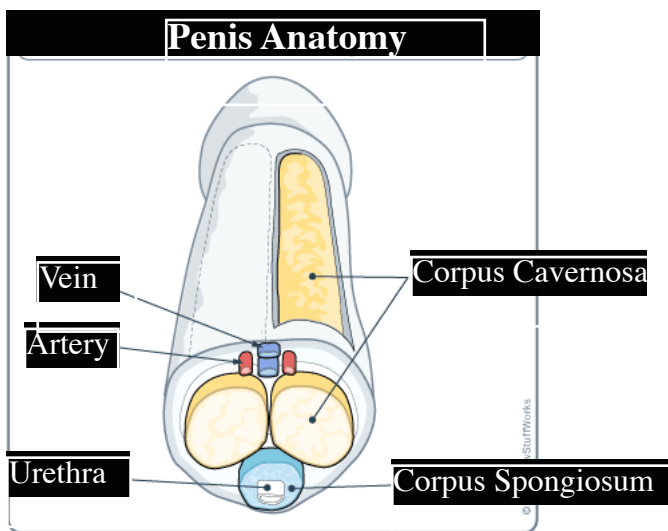
The VED® - The Vacuum Erection Device consists of two main parts:
the pump and constriction device.

Vacuum Pump ULTRA/CLASSIC/AXIS - This is used to create an erection in men with erectile dysfunction by means of an applied vacuum to the penis, which draws blood into the penile corpora cavernosa causing the penis to become erect and rigid. The two corpora cavernosa and corpus spongiosum are three expandable erectile tissues along the length of the penis which fill with blood during penile erection. The two corpora cavernosa lie along the penis shaft, from the pubic bones to the head of the penis, where they join. See diagram below.

Constriction Device - The Soft Touch™ seal and Constriction Rings are used to maintain penile rigidity in men with erectile dysfunction by restricting penile venous outflow after the patient has obtained an erection with the aid of a vacuum pump.

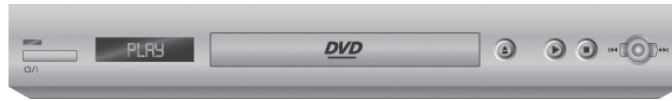
The VED® is designed to help create an erection sufficient to penetrate the vagina and have sexual intercourse. It is intended for use by men who have full or partial impotence.

Note: The VED® is not a contraceptive.



INSTRUCTIONAL DVD

Watch the Instructional DVD

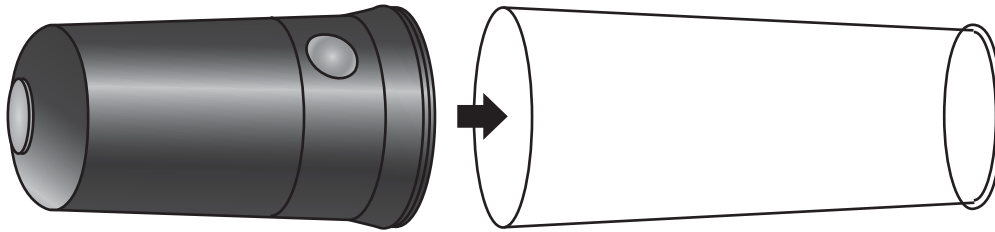


We recommend watching the Instructional DVD and reading the User Manual before using the VED®. The instructional DVD will show the steps for using the constriction devices included in your system. It is recommended that men practice achieving an erection several times using the VED® for sexual intercourse.

DIRECTIONS FOR USE - ULTRA/AXIS™

Using the VED® ULTRA/AXIS™

1. When using the VED® ULTRA/AXIS Battery-Powered Vacuum Pump, insert the battery powered vacuum pump into the wide end of the cylinder.
2. Make sure it is seated firmly to prevent air leakage.



Now the VED® ULTRA/AXIS is ready to be used to achieve an erection. When beginning it is best to use the VED® while in a standing position.

3. After coating the inside of the cylinder and your penis with lubricant, insert the penis into the cylinder so that it is lying along the bottom. Lubrication helps obtain the seal necessary to create a vacuum and allows the penis to slide easily inside the cylinder. Use only water based lubricant.
4. Position the cylinder over the penis, and place it firmly against the body to begin. In order to get an air tight seal, do not allow air to enter the end of the cylinder pressed against your body.
5. Hold the cylinder in place and begin the pumping action by depressing the gray switch on the top of the pump. The pump will stop automatically when no pressure is applied to the switch.
6. Operate the pump slowly. Press down the switch and slowly count for 3-5 seconds. Next let up on the button, the motor will stop, and again count for 3-5 seconds. It is this procedure that draws blood from your body filling your penis creating an erection. Repeat. **DO NOT RUSH THIS PART OF THE PROCEDURE.**
7. As blood is drawn into the penis, a stretching sensation will be felt as the penis enlarges. Discomfort can be expected during the first few uses. Once the penis fills with as much blood as it can hold, STOP!

Some men find that with the erection obtained using the VED®, the penis is wider, feels slightly cool, may appear darker, has prominent veins, and/or pivots at the base. These are all normal responses when using vacuum constriction.

DIRECTIONS FOR USE - CLASSIC™

Using the VED® CLASSIC™

1. When using the VED® CLASSIC™ (Manual Vacuum Pump) make sure the end cap is seated firmly in the cylinder.

2. Attach one end of the connecting tube to the vacuum pump and the other end to the nipple on the cylinder end cap. *Both ends on the connecting tube are the same fittings.* Be sure the fittings are snug to prevent air leakage.



Now the VED® CLASSIC is ready to be used to achieve an erection. When beginning it is best to use the VED® while in a standing position.

3. After coating the inside of the cylinder and your penis with lubricant, insert the penis into the cylinder so that it is lying along the bottom. Lubrication helps obtain the seal necessary to create a vacuum and allows the penis to slide easily inside the cylinder. Use only water based lubricant.

4. Position the cylinder over the penis, and place it firmly against the body to begin. In order to get an air tight seal, do not allow air to enter the end of the cylinder pressed against your body.

5. Hold the cylinder in place and begin the pumping action by squeezing the handle on the pump. The pump will stop automatically when no pressure is applied to the handle.

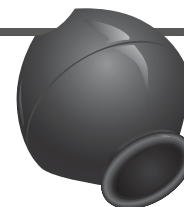
6. Operate the pump slowly. Squeeze the handle and slowly count for 3-5 seconds. Next stop squeezing, the vacuum will stop, and again count for 3-5 seconds. It is this procedure that draws blood from your body filling your penis creating an erection. Repeat. **DO NOT RUSH THIS PART OF THE PROCEDURE.**

7. As blood is drawn into the penis, a stretching sensation will be felt as the penis enlarges. Discomfort can be expected during the first few uses. Once the penis fills with as much blood as it can hold, STOP!

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NEW TECHNOLOGY - Sensation Seal™

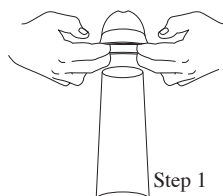
Installing the Sensation Seal



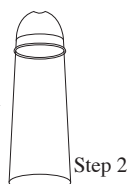
Penis Opening



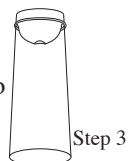
Rolled End



Step 1



Step 2



Step 3

1 Line up the rolled end of the Sensation Seal with the smaller end of the cylinder.

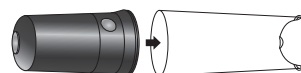
2 Using your fingers stretch the rolled end of the Seal over the outside rim of the cylinder opening.

3 Pull the Sensation Seal over the cylinder about 1-2 inches over the outside of the cylinder. Push the remaining Sensation Seal material into the cylinder with the penis opening facing down into the cylinder.

4 To make the length of the seal shorter pull the rolled end of the seal down about further over the outside rim.

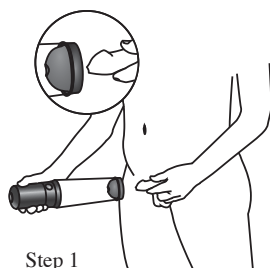


5 Connect the pump to the end of the cylinder.



♦(The battery operated pump is shown, but the Classic can be connected as well.)

Using Sensation Seal to Create an Erection



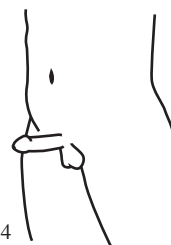
Step 1

Step 2



1 Once the Sensation Seal is loaded onto the end of the cylinder, place the tip of the flaccid penis against the opening at the center of the Sensation Seal.

2 At the beginning, gently push the cylinder against your body to help facilitate the seal. The penis will be drawn through the Sensation Seal into the cylinder and an erection will form. An air tight seal is created at the penis opening located at the center of the Sensation Seal.



Step 4

Step 3

3 As the vacuum is created within the cylinder and the penis expands in length and girth, the seal stretches allowing the penis to pass through the opening.

4 To remove the penis from the VED stop pumping, press the release valve, and gently pull the penis out of the Sensation Seal. The Seal should remain on the cylinder.

♦You may find the penis slides easier when placing VED lubricant on the inside opening of the Sensation Seal. (Note the expandable penis opening is available in four different sizes)

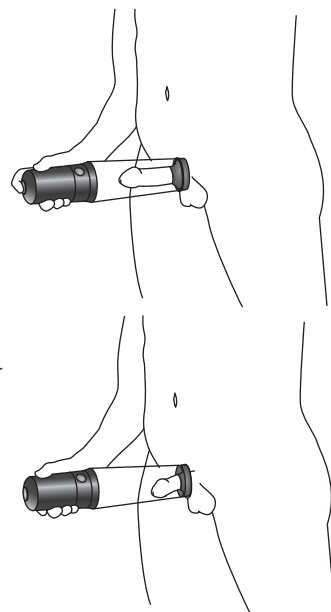
DIRECTIONS FOR VED THERAPY

VED Therapy is a daily exercise to pull blood into the penis. It's designed to replace lost nocturnal or night time erections. Follow these instructions or your physician's advice for therapy.

Do not use a constriction ring for daily VED therapy.

1. Maintain a comfortable erection in the cylinder with an air tight seal for 1 minute.
2. After the minute is up press the valve release located on your pump which will release the vacuum seal. This will cause the blood to flow out of your penis and back into your body.
3. Repeat steps 1 & 2 until you have achieved a total of 3-5 erections in a ten minute period.

Continue until you experience regular night time erections or spontaneous daytime erections.



**For comfort and protection, the vacuum pump has a built-in safety limiter valve to prevent excessive vacuum build-up.*

We recommend that men practice using the VED® to achieve a firm erection daily for at least two weeks before using it for intercourse. With continued practice, the length of time needed to achieve an erection will decrease, and the firmness of the erection will improve. This will also give your penis time to adjust to being filled with blood again.

USE WITH CONSTRICTION RINGS

Using The Constriction Devices

Using the Constriction Rings with the Loading Cone

(The Loading Cone is not available in all Systems, but can be purchased as an accessory separately)

1. To use the constriction ring, start out selecting the constriction ring with the largest number from the kit.

2. Remove the sizing insert from the end of the cylinder, putting it aside. (Fig. 1)

3. Place the adaptor ring into the end of the cylinder where you removed the sizing insert. (Fig. 2)

4. Insert the cone into the adaptor sleeve. Now you are ready to apply the constriction ring. (Fig. 3 & 4)

5. Next apply lubricant around the cone. (Fig. 5)

6. Place the center of the constriction ring over the cone head and slowly start sliding the ring over the cone toward the cylinder. (Fig. 6 & 7)

7. Completely slide the ring over the cylinder. (Fig. 8 & 9)



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6

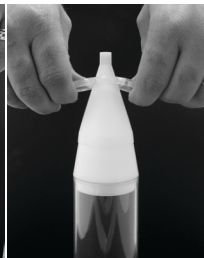


Figure 7

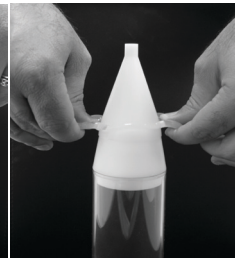


Figure 8

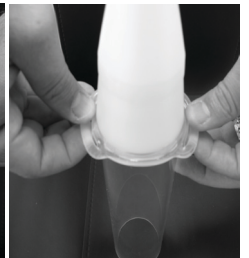
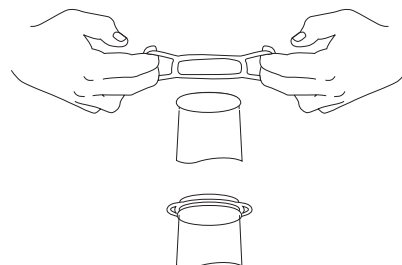


Figure 9

Note: If you do not have the Loading Cone System you may still stretch the Constriction Ring over the end to apply it to the cylinder.



USE WITH CONSTRICTION RINGS - (CON'T.)

8. Remove the cone and adaptor sleeve from the cylinder and replace the sizing insert you took off in the beginning. (*Fig. 10 & 11*)
9. Seat the ring as close to the cylinder edge as possible (*Fig. 12*). Now the pump, cylinder and constriction ring are ready for use to achieve and sustain an erection as instructed in the previous steps two and three.



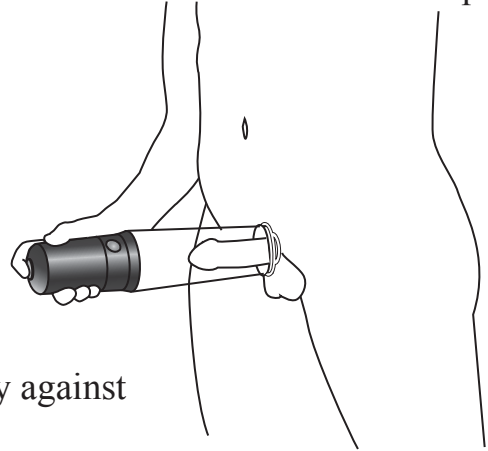
Figure 10



Figure 11



Figure 12



10. Position the cylinder over the penis and place it firmly against the body to create a seal.

NOTE: For ease, it may be necessary to stretch it or soak the constriction ring in warm water before attempting to place it onto the cylinder. The constriction rings are available in sizes 3 through 9. A #4, and #6 are usually standard with your VED. The larger the number, the less constriction it will provide. Start with the largest numbered ring provided and move to a lower numbered ring only if maintaining an erection is a problem. **Do not leave a constriction ring on longer than 30 minutes. Constriction rings are not contraceptive devices.**

11. Once an erection is achieved, transfer the constriction ring(s) from the end of the cylinder to the base of the penis. Pull the constriction ring(s) from the underside of the cylinder, being careful not to lose vacuum. (If more than one constriction ring is used, you may transfer the constriction rings either one at a time or together).

12. Release the vacuum and remove the cylinder from the penis, leaving the constriction ring in place (*Fig. 17*). The erection should be suitable for intercourse.

13. If, after removing the cylinder, the erection is not adequate, use a smaller ring, multiple rings, or combine the Soft Touch™ with one or more constriction rings. Call your Education Specialist for more information.

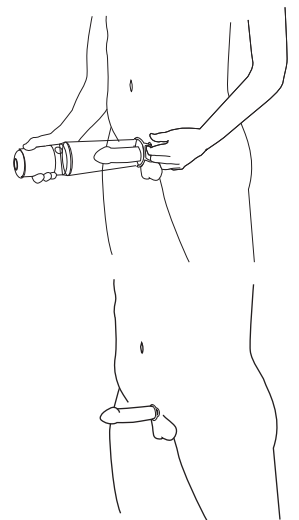


Figure 17

Some men find the erection obtained using the VED®, the penis is wider, feels slightly cool, may appear darker, has prominent veins, and/or pivots at the base. These are all normal responses when using vacuum constriction.

USE WITH SOFT TOUCH SEAL™

Using the Soft Touch™ Seal

1. Insert the cone onto the top of the applicator and place it on a flat surface (*Fig. 7*).

2. Apply a generous amount of Personal Lubricant to the cone and to the inside opening of the Soft Touch™ Seal.

3. Place the flat end of the thumbs on the raised edges of the Soft Touch™ Seal and position it over the cone (*Fig. 8*).

4. With one smooth motion, slide the Soft Touch all the way down to the bottom of the applicator. (*Fig. 9*).

5. Remove the cone from the sleeve (*Fig. 10*).

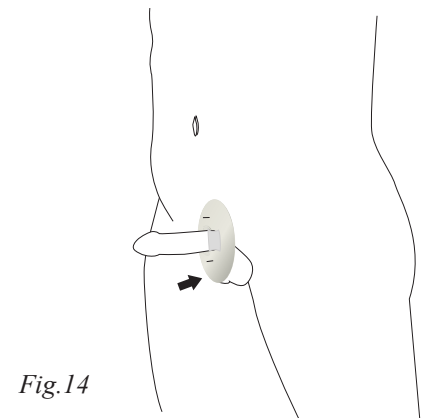
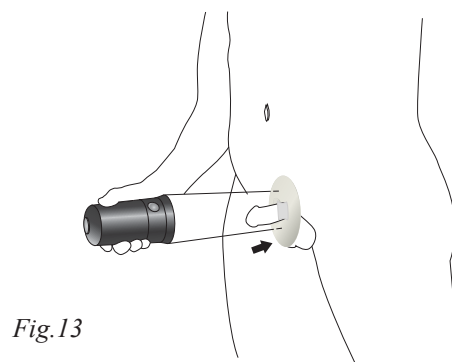
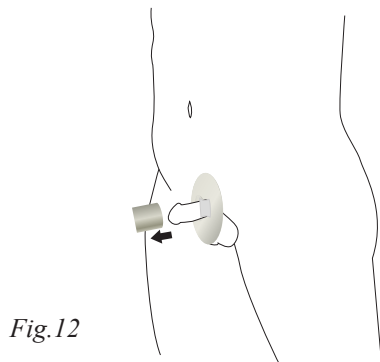
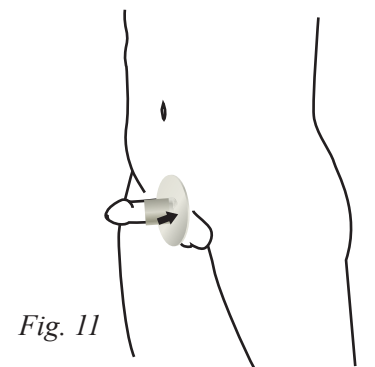
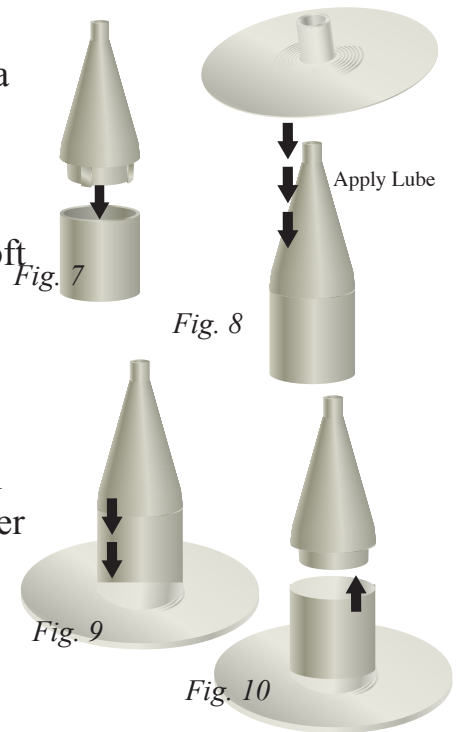
6. Place some lubrication around the base of the penis. Position the applicator onto the penis as close to the base as possible after removing the cone (*Fig 11*).

7. By holding the Soft Touch™ tightly against the body at the base of the penis and removing the applicator with the other hand, you will be able to transfer the Soft Touch™ from the applicator onto the penis smoothly (*Fig. 12*).

Now the pump, cylinder and Soft Touch are ready for use to achieve and sustain an erection as instructed in the previous page.

8. Position the cylinder over the penis and place it firmly against the Soft Touch Seal (*Fig 13*).

9. Once an erection is achieved, release the vacuum and remove the cylinder from the penis, leaving the Soft Touch™ in place (*Fig 14*).



Some men find that with the erection obtained using the VED®, the penis is wider, feels slightly cool, may appear darker, has prominent veins, and/or pivots at the base. These are all normal responses when using vacuum constriction.

CONSTRICTION DEVICE REMOVAL

Removing the Constriction Devices After Use

****Constriction may be left safely in place for up to 30 minutes.***

Constriction Rings

To remove the constriction ring(s), place the fingers in the outer loops and carefully pull them away from the body, allowing the blood flow to return. After several seconds, slide the constriction ring(s) off the penis.

SofTouch™ Seal

Carefully remove the SofTouch™ Seal by gripping the raised edges on both sides and slide it off the penis. The penis will return to its normal non-erect state once the constriction has been removed.

Warnings

- do not fall asleep while wearing the constriction ring, since prolonged use of the constriction ring may cause permanent injury to the penis.
- allow at least 60 minutes between uses, as more frequent use may increase the risk of injury to the penis.
- do not use constriction rings under the influence of alcohol or drugs, since such use may impair the user's judgment and increase the risk of injury to the penis.
- misuse of a constriction ring may cause bruising, painful injury, or permanent damage to the penis.
- constriction rings do not prevent pregnancy.
- do not use constriction devices with penile implants unless otherwise instructed by your physician.

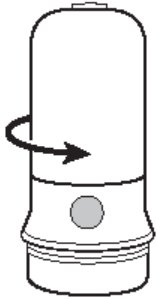
Precautions

- use of a constriction ring may aggravate already existing medical conditions such as Peyronie's disease (the formation of hardened tissue in the penis that causes pain, curvature, and distortion, usually during erection); priapism (persistent, usually painful erection of the penis as a consequence of disease and not related to sexual arousal); and urethral strictures (urethral stricture is an area of hardened tissue, which narrows the urethra sometimes making it difficult to urinate).
- limit use of the constriction ring to no longer than 30 minutes per use
- prolonged use of the constriction ring (i.e., without removal) may cause permanent injury to the penis
- device use may bruise or rupture the blood vessels within the penis or scrotum, resulting in petechiae (a small purplish spot on a body surface, such as the skin or a mucous membrane, caused by a minute hemorrhage (flow of blood from ruptured blood vessels), or the formation of a hematoma (localized swelling filled with blood resulting from a break in a blood vessel)).
- use the least constrictive ring size that maintains an erection, since excessive constriction could injure the penis.

MAINTAINING DEVICE EFFECTIVENESS

Instructions for changing the batteries in your VED® ULTRA™ Battery-Powered Vacuum Pump:

The pump operates on two AA batteries. Periodically, these batteries will need to be replaced. The procedure to replace the batteries is as follows:



1. Remove the pump cover by twisting it one half turn to the right.
2. Locate the batteries and remove them from the battery holder.
3. Place new batteries in the battery holder. Be sure the batteries are connected properly.
4. Depress the button located at the top of the pump to make sure the batteries are functioning properly.
5. Refit the pump cover on the pump and turn the cover to the left until it is locked firmly in place. The pump is now ready for use.

CLEANING THE VED® ULTRA/AXIS/CLASSIC™

VED® ULTRA™ with Battery-Powered Vacuum Pump (motorized vacuum pump model)

☞ After using the VED® ULTRA™ clean all components, **except the battery-powered vacuum pump**, in warm soapy water and allow to air dry.

☞ Be sure to remove the battery powered vacuum pump from the cylinder before cleaning.

☞ To remove the battery pump from the cylinder, grasp the cylinder firmly and gently twist the pump upward in a clockwise direction.

☞ Wipe the outside of the battery-powered vacuum pump with a dry cloth, but do not immerse it in any type of fluid or it will be damaged beyond repair.

☞ Never wash any VED® ULTRA™ component in a dishwasher, nor clean them with an alcohol solution. Never put components in a microwave.

VED® CLASSIC™ Manual Vacuum Pump (hand-powered manual vacuum pump model)

☞ After using the VED® CLASSIC™, clean all components, **except the pump and connecting tube**, in warm soapy water and allow to air dry.

☞ Remove the cylinder end cap for ease in cleaning.

☞ Wipe the VED® CLASSIC™ vacuum pump with a dry cloth, but do not immerse it in any type of fluid or it will be damaged beyond repair.

☞ Never wash any VED® CLASSIC™ component in a dishwasher, nor clean them with an alcohol solution. Never put components in a microwave.

REPLACEMENT PARTS

There are three ways to order replacement parts and accessories:

1. Mail or fax the enclosed order form to Firma Medical.
2. Call our Customer Service at 1-800-771-9263.
3. Visit our online store at www.firmamedical.com (coming soon)

CONTRAINDICATIONS

Do not use VED® CLASSIC/ULTRA™ if:

1. You are under the influence of alcohol or drugs.
2. You experience persistent pain in the penis.
3. There are sores or ulcers on the penis.
4. There are black or blue areas (ecchymosis) on the penis.
5. There is any unusual swelling of the penis.

Medical conditions that may affect use of VED® CLASSIC/ULTRA™ are:

1. History of sickle cell trait or other bleeding disorders.
2. History of priapism (prolonged erection).
3. Coagulation defects.
4. Tumors of the penis.
5. Removed penile implant.
6. Physical conditions that make sexual intercourse inadvisable.

Consult a physician if you have questions regarding your medical history and how it may affect your use of the VED®. External penile rigidity devices are over-the-counter (OTC) devices; however, they are often used in consultation with a physician. Manufacturers may elect to restrict distribution of their devices through professional channels and healthcare providers may actually prescribe these devices to patients. External penile rigidity devices used in consultation with a physician rely on the medical experience and knowledge of the physician in performing an evaluation of the patient, determining whether an external penile rigidity device is appropriate for the patient, and thoroughly discussing any instructions unique to that patient's circumstances.

PRECAUTIONS

Consult a physician should any complications present, and discontinue use of the device if such conditions persist. Alternative treatments such as counseling, drug therapy, hormonal therapy, vascular surgery, and implanted prosthetic devices also exist. Contact your physician for more information regarding these alternative treatments.

- The user should apply the minimum amount of vacuum pressure necessary to achieve an erection.
- The user should stop using the vacuum pump if pain occurs.
- Vacuum pumps should not be used under the influence of alcohol or drugs.
- Use of the vacuum pump may bruise or rupture the blood vessels either immediately below the surface of the skin or within the deep structures of the penis or scrotum, resulting in hemorrhage and/or the formation of a hemorrhage.
- Misuse of a vacuum pump may aggravate already existing medical conditions such as Peyronie's disease, priapism, and urethral strictures.
- Misuse of the vacuum pump could result in swelling of the penis and/or serious permanent injury to the penis.
- Do not use an electrically powered vacuum pump in or near water.

Warnings and Cautionary Statements when using VED®

•If you have symptoms of erectile dysfunction, (i.e. inability to achieve an erection that is sufficient for sexual intercourse), consult a physician prior to using this device to avoid a potentially harmful delay in diagnosing any of the common causes of this condition, such as diabetes, multiple sclerosis, cirrhosis of the liver, chronic renal failure, or alcoholism.

- Do not use the device if you have decreased sensation of pain in the area of the penis.
- Use of petroleum based lubricants with your VED® may result in damage to the device.

REFERENCES

FDA Draft Guidance For the Content of Premarket Notification For External Penile Rigidity Devices, dated March 21, 1995.
Patient Handout (for vacuum devices and constriction rings), December 1991,
Contemporary Urology.

THINGS TO KNOW

For some men, one or more of the following differences may be noted.

The penis may feel slightly cool.

This is because the constriction decreases the amount of blood flowing into the penis.

The penis is bigger around (larger girth) than during a normal erection.

This is because all the tissues of the penis beyond the constriction are filled with blood.

The penis may appear darker and the veins will stand out.

This is because blood is trapped in the penis by the constriction.

The penis will pivot at its base.

The penis is rigid only beyond the constriction. During a normal erection, the hardness extends back into the body.

The semen may not come out when you reach an orgasm.

The urethra may be blocked by the pressure of constriction, or in most instances if you had prostate surgery you will not ejaculate.

NOTE: The VED® CLASSIC/ULTRA™ is not a contraceptive.

FREQUENTLY ASKED QUESTIONS

Why do I count 1 - 2 - 3 holding the button and then 1 - 2 - 3 without holding the button?

The first count pulls blood into the penis while the second count without using the button allows time for the skin of the penis to expand allowing room for the blood. This process continues with each count.

When do I stop counting 1 - 2 - 3? What size should my penis be when I stop counting?

Each time you use the device you will reach a point where you feel the vacuum will no longer increase the penis size. You will likely know this more by feel than by sight. This is when you should stop. Note that this might not be the size of full erections you have had previously but as you continue to use the device, the maximum size may increase to that of your full erection.

Why does my penis immediately become small again when I remove the cylinder?

Because the blood has been drawn into the penis through the pressure of the vacuum and returns once the vacuum is released.

Why didn't the rings work for me to have intercourse the first night that I used the system?

This is probably just a matter of comfort and practice. Many men find it helpful to try the device by themselves to get used to it before attempting intercourse with it. We usually recommend two weeks of practice.

FREQUENTLY ASKED QUESTIONS (cont.)

Why are my erections not hard?

The degree of firmness depends on many factors and the firmness of the erections created with the VED® may increase with use and practice. Remember that the goal of the VED is to create an erection sufficiently firm to penetrate your partner.

Will I always need to use a ring or the Soft Touch Seal in order to have intercourse?

This is different for every man but some men find that using the VED without the constriction ring can help create an erection sufficient for penetration. The constriction devices are used only if the blood is not staying in the penis after the vacuum is turned off.

Why do I need to use the lubricant that Firma Medical sells?

The lubricant we provide was created to be used with our VED. Many over the counter lubricants are petroleum based or too thin to hold up under the pressure created by the vacuum. It's possible for particles of these to be pulled into the vacuum head which could decrease the life of the motor.

Why do the rings hurt?

The rings may cause some discomfort but if it causes pain, you probably need a larger size. The rings come in various sizes. Call 1-800-771-9263 or visit www.firmamedical.com to order larger constriction rings.

Why does my penis hurt when I push the vacuum button?

If the count of 1, 2, 3 causes discomfort, try counting just to two, or even one, to see if that is more comfortable. You can also lengthen the time in between activating the device (when the device is not running). If this doesn't help and you are still experiencing pain, contact your physician.

Why did the Soft Touch Seal tear when I barely pulled on it?

The Soft Touch Seal is very thin. It needs to be thin in order to perform as designed. After liberal lubrication, we suggest that it be pulled over the head of the cone by placing each thumb on the raised edges and gently pull downward with equal stretching on both sides until you reach the base of the applicator. The Soft Touch™ Seals can be replaced by calling 1-800-771-9263 or visiting www.firmamedical.com.

How much lubricant should I use?

Use enough to generously cover an area about the size of a quarter. Place this on your longest finger and coat the inside of the cylinder each time before use. Additional lubricant can be used to coat the rim of the cylinder where it comes in contact with the body to provide a tighter seal.

Do I need to pay for something if it breaks?

The cylinder and the vacuum head are covered under warranty and can be replaced if they break within the warranted time frame. The other pieces may require replacement. To order replacement parts, call 1-800-771-9263 or visit www.firmamedical.com.

Is my pubic hair supposed to be pulled into the cylinder too?

Men should groom their pubic area for a better seal and comfort. This can be done by trimming or shaving.

PROBLEM SOLVING

<i>Problem</i>	<i>Likely Cause</i>
No Erection	No vacuum due to air leak caused by a poor seal, inadequate lubrication, or excessive pubic hair.
Partial Erection	Incorrect cylinder size, incorrect sizing insert, not enough practice sessions.
Rapid Loss of Erection (in less than 5 minutes)	Vacuum lost because of air leak from faulty equipment, poor seal, inadequate lubrication, or excessive pubic hair.
Delayed Loss of Erection (after 5 to 10 minutes)	Insufficient tension from constriction rings.
Pulling of the Skin on the Scrotum	Lubricant on scrotum, improper pumping technique, inexperience with system, cylinder opening too large, cylinder not positioned properly against underside of the penis.
Discomfort or Pain During Pumping	Too rapid pumping. Pulling scrotal tissue.
Discomfort or Pain from Constriction Ring	Constriction ring too small. User anxiety.
Discomfort or Pain During Intercourse	Inadequate lubrication. Pressure on a sensitive area.
Discomfort or Pain During Ejaculation	Long period of abstinence. Infection or inflammation of the prostate gland.
Burning Sensation, Irritation, or Bruising	Too rapid pumping or over-pumping.
Penis Feels Cold (to you or your partner)	Constriction of blood flow to penis, lubrication.
Penis Pivots at its Base	Constriction of blood flow to penis.

PROBLEM SOLVING (continued)

If you need assistance, call customer service at 817-473-7473 or 800-771-9263.

<i>Remedy</i>	<i>Comments</i>
Use more lubricant, apply firm pressure to the body. Trim pubic hair. Check the VED® CLASSIC/ULTRA™ for air leaks.	Problem is most often associated with inexperience; it resolves as you become more adept at using the device.
More practice using the VED® CLASSIC/ULTRA™.	Problem most often improves with continued use of the VED® CLASSIC/ULTRA™.
Same as “No Erection”. Also use sizing insert. Use smaller constriction ring or use multiple rings. Transfer constriction ring very carefully. Trim pubic hair.	Requires that you experiment with varying sizes of constriction rings. See a physician if you need help or support to persevere.
Use smaller constriction ring or a combination of constriction rings and Softouch™.	Call Firma Medical to order constriction rings in more sizes. Rings are offered in sizes 3 through 10.
Remove lubricant from the scrotum. Use sizing insert. Use double pump procedure as noted in the instructions. Angle cylinder downward during pumping. Continue practice sessions.	Problem may disappear as you become more adept at using the VED® CLASSIC/ULTRA™.
Slower pumping. Angle cylinder downward during pumping.	Problem usually resolves as you become more adept at using the VED®.
Use larger constriction ring.	Problem usually resolves as you continue to use the device.
Apply more lubrication. Change positions.	
Continue use of the VED®. If pain or discomfort persists, consult a physician.	Problem usually resolves as you continue to use the VED®. If pain or discomfort persists, consult a physician.
Slower pumping, fewer pumps.	Consult a physician if this problem persists past the first few practice sessions.
Wash off lubricant or warm the lubricant before use.	Partners can use a water soluble warming lubricant for added benefit. Call our office for suggestions.
If manageable, apply the device after you have a partial erection.	

WARRANTY AND RETURNS

One Year Limited Warranty for Over the Counter VED

Firma Medical guarantees the VED® CLASSIC/ULTRA™ from mechanical failure resulting from defective parts and/or workmanship for one year from the date of purchase. The warranty includes the major components of the product: VED® CLASSIC/ULTRA™ vacuum pump and cylinder. Should any of the components listed fail to function properly, return the damaged part(s) and Firma will replace the part(s) free of charge. The following restrictions apply:

- Items such as the SofTouch™ Constriction Seal, Constriction Rings, VED® Personal Lubricant and batteries are not included in this warranty.
- The warranty does not cover damage due to improper handling, cleaning, or misuse of the product, or failure to follow the instructions in the Directions for Use.
- Products tampered with or altered in any way are not covered in the warranty.

*This warranty is in lieu of any other warranties, either expressed or implied.

Five Year Limited Warranty for Rx VED (Medicare Beneficiaries)

Every Rx VED system sold by Firma Medical carries a 5-year manufacturer's warranty. This warranty will cover the pump (manual and battery operated) and the cylinder against manufacturer defects for 5 years. Firma Medical will notify all Medicare beneficiaries of the warranty coverage and we will honor all warranties under applicable law. All warranted Medicare and Rx equipment will be replaced, free of charge, under this warranty, provided your account is in good standing.

Customer Return Policy

Contact Firma Medical for full details and restrictions which apply to a Return Authorization. You must contact the main office and acquire an RA Number before returning the product. In many instances, a problem can be corrected by adjusting the manner in which the product is used. Our clinical specialists can provide "user tips" which often overcome mechanical difficulties encountered by the user; this may prevent unnecessary inconvenience.

- The products Firma Medical manufactures are considered sanitary and are for single person use.
- Products are never refurbished and for that reason items purchased such as replacement parts, constriction rings, SofTouch™ Constriction Seals, and constriction bands, are not returnable.

COMPLAINT PROCESS

Once Firma Medical receives a complaint either verbally, electronically, by fax, or by letter, a resolution will be made as quickly as the concern requires, but no more than 14 calendar days after the receipt of the grievance.

IMPORTANT CONTACT INFORMATION

Our Organization

Firma Medical, LP
99 Regency Pkwy, Ste. 203
Mansfield, TX 76063
Toll Free: 800-771-9263
Direct: 817-473-7473
Fax: 817-473-9639
www.firmamedical.com

Accreditation Company

The Compliance Team, INC.
P.O. Box 160, 905 Sheble Ln, Ste. 102
Spring House, PA 19477
Toll Free Complaint Line: 888-291-5353
Phone: 215-654-9110

State Agency

Office for Civil Rights, U.S. DHHS
1301 Young St., Ste. 1169
Dallas, TX 75202
Phone: 214-767-4056
www.hhs.gov/ocr/discrimhowtofile.pdf

Federal Agencies

Office of Inspector General
Dept. of Health & Human Services
Attn: Hotline
330 Independence Ave SW
Washington, DC 20201
Toll Free: 800-447-8477
Fax: 800-223-8164
Email: HHSTips@oig.hhs.gov

Medicare

1-800-MEDICARE, www.cms.hhs.gov

CMS MEDICARE DMEPOS SUPPLIER STANDARDS

Note: This list is an abbreviated version of the application certification standards that every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. pt. 424, sec 424.57(c) and were effective on December 11, 2000.

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, or cell phone is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from calling beneficiaries in order to solicit new business.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare-covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e. the supplier may not sell or allow another entity to use its Medicare Supplier Billing Number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.

PATIENT RIGHTS AND RESPONSIBILITIES

As a client/patient of Firma Medical, you may exercise the following rights regardless of age, gender, economic status, race, color, national origin, religion, ethnicity, disability, educational background, marital status, sexual orientation, or source of payment for care. These rights also apply to the person who has legal responsibility for decisions concerning your care if you are unable to make decisions yourself.

I. The Right to information

You have the right to receive accurate and easily understood information concerning our product and service, to include the to charges, out-of-pocket cost, and possible third party payment.

II. The Right to Choose

You have the right to a choice of medical equipment providers and healthcare providers that are sufficient to provide you with access to appropriate high-quality health care.

III. Access to Emergency Services

You have the right to access emergency health services when and where the need arises.

IV. Participation in Treatment Decisions

You have the right to know all your treatment options and to participate in decisions about your care. You have the right to refuse service/care after the consequences of refusing are fully presented.

V. Service without Discrimination

You have the right to be treated with respect, consideration, and recognition of dignity and individuality.

VI. The Right to Privacy

You have the right to talk in confidence with Firma Medical's identifiable representatives and to have your private health care information protected. You have the right to be advised of our policies regarding the disclosure of clinical records.

VII. Complaints and Appeals

You have the right to voice grievances/complaints regarding the service/product and to have a fast, fair, and objective review of any complaint you have against Firma Medical.

Just as Firma Medical has responsibilities to its staff and clientele, so too, does the patient have responsibilities when under the care of Firma Medical. These include the following:

I. Participation in Care and Accurate Information

- a. You have the responsibility to provide accurate and current health information and follow the instructions outlined for the proper use of the equipment/device.
- b. You are responsible for your actions if you do not follow the outlined instructions.

II. Financial Obligations

- a. You have the responsibility to provide accurate information with regards to your health insurance coverage.
- b. You have the responsibility to give accurate financial information and to pay your bill promptly.

III. Appropriate Conduct

You have the responsibility to be considerate and cooperative of others and avoid discrimination against health care providers because of race, color, gender, ethnicity, national origin, religious affliction or sexual orientation.

If you believe that any of your rights have been violated, please call the State Health Insurance Assistance Program in your State.

NOTES

VED REGISTRY CHECKLIST

Please remember to send in your VED Registry Questionnaires.

☐ Baseline Questionnaire Date Sent: _____
Very important to have a baseline or starting point.

☐ 3 Month Questionnaire Date Sent: _____

☐ 6 Month Questionnaire Date Sent: _____

☐ 12 Month Questionnaire Date Sent: _____



DIRECTIONS FOR USE

VED[®] ULTRA™ (Battery-powered Vacuum Pump)
CLASSIC (Manual Vacuum Pump)
Vacuum Erection Device

Manufactured and distributed by:



99 Regency Parkway, Suite 203
Mansfield, TX 76063

Office: 817- 473-7473
Toll Free: 800-771-9263
Fax: 817- 473-9639
www.firmamedical.com
email: sales@firmamedical.com